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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,435	11/12/2003	David E. Lanar	003/285/SAP	7145

7590 08/13/2008

ATTN: MCMR-JA (Ms. Elizabeth Arwine-PATTENT ATTY)
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EXAMINER	
VOGEL, NANCY TREPTOW	
ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
08/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,435	LANAR ET AL.	
	Examiner	Art Unit	
	NANCY VOGEL	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,5,9-39,42,43,45-49,52,53,57,58,62,63,65-90 and 93* is/are pending in the application.

4a) Of the above claim(s) *5,10-38,43,45-48,53,58,63,65-73,77-85 and 88-90* is/are withdrawn from consideration.

5)☒ Claim(s) *4,9,39,42,49,52,57,62,74,75 and 93* is/are allowed.

6)☒ Claim(s) *76,86 and 87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 4, 9, 39, 42, 49, 52, 57 , 62 and 93 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 74-76, and 86-87, directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 5, 10-38, 43, 45-48, 53, 58, 63, 65-73, 77-85, 88-90, directed to the invention(s) of recombinant LSA-NRC polypeptides other than that shown in SEQ ID NO:26 (i.e. claims 4), DNA and vectors, and methods which use said LSA-NRC polypeptides other than that shown in SEQ ID NO:26 (i.e. claim 4), do not require all the limitations of an allowable product claim, and have NOT been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between groups I limited to the LSA-NRC of SEQ ID NO:26 and VIII, limited to methods using the LSA-NRC of SEQ ID NO:26, as set forth in the Office action mailed on 6/16/06 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C.

121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application contains claims 5, 10-38, 43, 45-48, 53, 58, 63, 65-73, 77-85, 88-90, drawn to an invention nonelected with traverse in the reply filed on 12/1/06 A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Applicants have stated that they will submit the corrected oath when it is available to them. Therefore, the issue of the defective oath remains.

Specification

The disclosure is objected to because of the following informalities: the amendments to page 27 at lines 25 and 26 are improper, since added text must be underlined. See MPEP 714.

Appropriate correction is required.

The following is a new rejection necessitated by applicant's amendments:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 86 and 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is a method for inducing a protective response to malaria in an animal using the LSA-NRC of claim 4 in an effective amount. Since a "protective response to malaria" is the action expected from an effective vaccine, the nature of the invention is essentially a method of vaccinating against malaria.

The state of the prior art shows that vaccination against malaria, to provide a protective response, is very difficult and elusive. For example Druihle et al. (PLoS Medicine, 2, 11, 1135-1144, 2005) disclose that development of a malaria vaccine has been limited by major conceptual and practical difficulties, and the relevance of animal models is imprecise (page 1136, lines 1-7). Therefore, Druihle et al. disclose that one cannot predict from animal models, the efficacy of any vaccine candidate. Druihle et al. further disclose that such factors as immune memory, high polymorphism in the regions of immunological interest, low antigenicity without the use of powerful and hence toxic adjuvants, short duration of immune responses, and lack of bioassays able to reflect protection and hence to guide preclinical steps (see page 1143, second column). Phillips et al. (Clin. Microbiol. Rev., Jan. 2001, 14(1): 208-226), disclose that a malaria vaccine represents a major challenge, even with unlimited resources to devote to the task" and discloses that development of a vaccine is "particularly difficult (page 218) and "selecting targets for vaccine-induced immunity and the corresponding peptides with which to induce that immunity has been extremely difficult. Many of the immunodominant antigens in natural infections have not been shown to be targets of protective immunity (page 218). The reference discloses such complicating facts as animal models are not ideal for evaluating vaccine candidates to be used in humans,

and there is no suitable in vitro assay for measuring levels of protective immunity in vivo, for example, being able to relate levels of antibody to a specific antigen to the level of protection in vivo. Therefore, the only way of determining , at present, the efficacy of a vaccine candidate is to set up human trials, involving natural or experimental challenge, which are very expensive and take a long time to complete and evaluate" (page 218).

The specification contains no working examples of efficacy of the disclosed polypeptide in providing a protective response to malaria in any mammal.

The specification provides only general guidance for methods of immunization.

The quantity of experimentation, as disclosed at page 1143 of Druihle et al. needed to develop a vaccine candidate which would provide a protective response to malaria, is extensive and unpredictable.

Therefore, it is maintained that the enablement requirement for the claims 86 and 87 has not been satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 76 is dependent on claim 75, which recites a method. However, claim 76 is drawn to a composition, and therefore it cannot be determined what is intended by

the claim. It has been assumed in the interest of compact prosecution that it is intended that the claim recite: "The method of claim 75, wherein said adjuvant is selected from the group consisting of Montanide, and alum."

Claims 4, 9, 39, 42, 49, 52, 57, 62, 74, 75 and 93 are allowed.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
8/7/08

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